

# **SPL Process Meeting Meeting Minutes September 11, 2013**

Chair of today's meeting: Pat Cowall

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

\*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

\*\*\*\*\*

## **Discussion Topics:**

1. D&B data issues – Dale lanetti (Merck) is part of a pilot program and had a number of issues. Dale sent whole file to D&B to get their help in resolving their issues.
  - D&B - compared all data from all sites – so that they could determine the differences.
  - Talked through all the issues. D&B is investigating several of their issues. They are going to talk to FDA to determine if there is some flexibility in terms of allowing differences.
  - Merck will not change addresses or names, but will make minor changes in addresses if the address is still consistent. Merck also needs several new DUNS numbers because the addresses didn't match up.

\*\*\*Hold to next meeting

## **New Business:**

2. Dale lanetti: I was wondering if anyone in the group has had the opportunity to request a new FEI number for a site, and exactly what the process is. I have heard different stories and would like to know if anyone has actually done it since SPL has been in use.

\*\*\*Hold to next meeting

Charisse Kasser was involved with writing the new guidance. The FEI number will not go away, at least in the near future. At any event, the FEI will be used internally at FDA in their computer systems.

Many FDA ORA systems use the FEI numbers, so the FEI number will stay.

3. Validation Issues: From Lonnie's email, please report ANY issue with Pragmatic Data Validator Lite to Pragmatic Data, LLC using their e-mail address [spl@pragmaticdata.com](mailto:spl@pragmaticdata.com).

Has anyone had problems? No one spoke up.

4. Marketing date: Tricia Pasek (Perrigo)

I am sending this email to inquire if anyone else who submits drug listings for OTC ANDA or OTC monograph products (through CDER) for their customers has ever had a problem with duplicate NDCs.

**Here is the scenario:**

- We have customer "A" that we manufacture a drug product for, we assign their NDCs and we also drug list for them.
- Customer "A" has a supplier #2 that also manufactures drug product, assigns NDCs and drug lists for them.
- When one manufacturer tries to drug list, they find that another company has already electronically drug listed the exact same NDC (segment 1 and segment 2). This results in NDC duplication for the manufacturer that didn't electronically drug list the NDC first.

Has anyone else ever had this issue and if so, how do you handle it?

We used to have this issue quite often, but have set some processes in place that help minimize this situation. Our processes cannot be 100% effective, but do help to minimize the situation to the best of OUR ability.

**June Moore (Rhodes) responded:**

I send in the approved spl with a future market start date of 5 years to give time to launch (just in case there are problems not for seen), then when ready to launch I send in the new spl with the correct date of launch. You will send in the spl to OC and not CDER, hope this helps.

She also corresponded with several others people who had similar problems. The distributors do not want to manage their own NDC codes, or they don't understand the rules around assigning NDC codes. Thus, the manufacturers are assigning an NDC number using the customer's labeler code. The problem is that manufacturers do not have any visibility on which NDCs are being used by other suppliers. Therefore you have duplicate NDCs. How can you avoid this problem?

- Visibility: How do you see the NDC numbers? Go to Daily Med and do a search to see if the NDC is being used. (This usually works, but sometimes 2 suppliers are trying to create new NDCs at the same time.)
- Submit a "mock" SPL file with an image that says "no image available" with a market start date way in the future. This should result in a validation error if the NDC code is already in use by another company.

5. Market Start Date (Marylyn Oparaugo (Banner))

The approval letter says “As soon as possible, but no later than 14 days from the date of the approval, submit automated drug listing”.

Do you update the approved spl with a future market start date and submit within 14 days or wait closer to launch as the product is not yet in commercial distribution as per the regulations? Any thoughts on this will be appreciated. I tried querying the prior spl group minutes but still not clear on when this activity should be performed for a newly approved product.

Further information:

The language in the approval letter is related to the content of labeling (Electronic Labeling Rule,) not drug listing.

As stated in the May 2009 Guidance for Industry – Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing, the eLIST system is utilized for post-approval content of labeling submissions. See excerpt below:

“SPL format is already used for submission of content of labeling in electronic format as required in New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Biological License Applications (BLAs), and annual reports on approved drugs.<sup>12</sup> See *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (April 2005).<sup>13</sup> Because the content of labeling required under those provisions can be duplicative in content and format (SPL) of the labeling required to be submitted electronically as part of listing information, FDA encourages applicants to submit this labeling material, and updates, primarily through the drug establishment registration and drug listing system. **Rather than make duplicate submissions, applicants are then encouraged to reference the SPL labeling file submitted through the electronic drug registration and listing system in making labeling updates to applications under the content of labeling requirements. FDA intends to issue guidance that will address this issue in further detail.**

Beginning June 1, 2009, FDA intends to use the electronic drug establishment registration and listing system as the source of SPL to **provide postapproval content of labeling for public access on the Web**, making that system the key repository of this information.”

6. Market Start Date (Gil Granados-SanofiPasteur)

For CBER-regulated products, what date is use for the marketing start date of a licensed product?

- For example, approval of a new supplement? Do you use the approval date of the supplement? The SPL would be used for drug listing purposes (through the OC).

The question revolves around implementation of a revised PI and packaging whereby the package (including the PI) has not been implemented for use.

\*\*\*\*\*

Response:

CDER: Approval letters state 14 days. We consider implementation to be when the labeling is posted to our web site.

If a new product isn't being immediately, they also put in a blank image in the PDP section and put in a future start date in the DPL data section. Then they submit another drug listing with correct information before launch.

CBER: HOLD ....to get comments from others on CBER side.

7. Kathy Linn (Hospira)

Issue: the revision dates in the highlights section that appears in the Daily Med does not appear correctly.

Their software has been updated to include the latest date from any section in Sections 1-17. Prior to this, the date came from the revision date. This was a recent change in the SPL stylesheet. However Daily Med may not have been updated yet.

The revision date is the most recent date assigned to sections 1 to 17....not from other sections.

There is an issue with the algorithm that recognizes the date in each of the sections. If the date is 10, 11, or 12 (ie Oct – Dec) then the algorithm doesn't it as being a valid date. It then populated the latest date been the 1 and 9 month.

Contact John Kilbourne at [Kilbourj@mail.nlm.nih.gov](mailto:Kilbourj@mail.nlm.nih.gov) (took over for Stewart Nelson) at Daily Med to tell them about the problem. It might be good to copy Terry and Pat

8. What date should you put into draft labeling:

DRAFT labeling can still use 00000000

9. Has anyone done a product that contains an inner bottle that is common across customers (with no NDC numbers) and only the outer bottle has a customer specific label with the specific NDC of the customer. Does anyone have experience? What are the implications for drug listing?

CDER: This will work for CDER products, because the inner NDC does not have to be included.....yet.

CBER: This won't work, because each packaging level needs to have an NDC.

- They would not print an NDC on the inner label.
- In essence, you are just repackaging a product for a customer
- Have they put in a source code?

10. Howard Shatz for a client. Optional functionality to allow including the market start date on individual package sizes. We've been told that you shouldn't put in a package date yet (implementation date TBD).

### **Announcements:**

New Draft Guidance: Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration

<http://www.fda.gov/downloads/GuidanceComplianceRegulatoryInformation/Guidances/UCM367199.pdf>

### **ESG Issue**

- ESG REG has confirmed that there is now a known issue with ESG WebTrader's Acknowledgements.
- There is a problem where user Acknowledgements are not displayed in the MySubmissions Screen, but sent to the Other Documents Folder in some but not all cases.
- ESG REG are aware of the problem and are working to fix it. In the meantime, please keep this in mind when sending submissions via the FDA WebTrader to check your Other Documents Folder for the Acknowledgements.

### **SPL/DailyMed Jamboree Workshop**

NLM is sponsoring a public meeting, "SPL/DailyMed Jamboree Workshop, on October 28, 8:30 to 3:30 – Using DailyMed Drug Product Label Data". Representatives from the brand name, generic name and OTC drug industries will speak, as well as the FDA, the NLM and possibly other government agencies.

- Terry Brunone, Marcia Howard, Virginia Hogan (generics) and others will be presenting.
- Note: I tried to register last week and the online spots were full. I was put on a wait list. There were still spots available to attend in person, as of last week.
- Marcia Howard would like to know of any unique ways they are using information from Daily Med.

**DIA Labeling Conference** -- focusing on a number of global labeling topics: how to write device labeling, patient labeling, new EU Pharmacovigilance influence on labeling, Health Canada, PMDA, etc. Steve Bass will be sending more information on this.

Timing: April 8-10, 2014

Where: Washington area